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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,964	07/08/2003	Hector F. DeLuca	1256-00777	8876

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/614,964	DELUCA ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 22 is/are pending in the application.

4a) Of the above claim(s) 1-21 and 23-39 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 22 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/24/2003
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restrictions

Applicant's election of Group V (claim 22) in the reply filed on 9/25/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

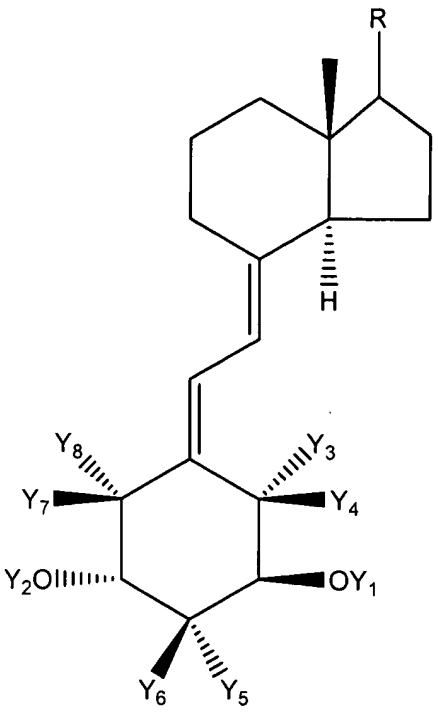
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca, et al. (US Patent No. 6114317).

DeLuca et al. teach, in the abstract, a method of modifying or altering the structure of a 1α-hydroxylated vitamin D compound to increase its biological activity. DeLuca et al. teach, in col. 4 line 66 to col. 6 line 44, novel 1a-hydroxylated vitamin D analogs of formula I. Specifically in col. 4 line 66 to col. 6 line 44 it is stated:

"Structurally these novel analogs are characterized by the general formula I shown below:



where Y.sub.1 and Y.sub.2, which may be the same or different, are each selected from the group consisting of hydrogen and a hydroxy-protecting group; where Y.sub.3, Y.sub.4, Y.sub.5, Y.sub.6, Y.sub.7 and Y.sub.8, which may be the same or different, are each selected from the group consisting of hydrogen, a methyl group or substituted methyl group of the formula --CR.sub.1 R.sub.2 R.sub.3, an amino group or substituted amino group of the formula --NR.sub.1 R.sub.2, a phosphino group or substituted phosphino group of the formula --PR.sub.1 R.sub.2, an alkylsulfinyl group, an arylsulfinyl group, an alkylsulfonyl group, an arylsulfonyl group, and aryl, where R.sub.1, R.sub.2 and R.sub.3 are each independently selected from the group consisting of hydrogen, C.sub.1-5 alkyl, hydroxyalkyl, aminoalkyl, halogenalkyl, alkoxyalkyl, aryloxyalkyl, aryl, halogen, hydroxyl, protected hydroxy, alkoxyl, aryloxyl, acyl, an amino group, an alkyl substituted amino group, and an aryl substituted amino group, and

where R.sub.1 and R.sub.2 taken together represent an oxo group or a group --(CH.sub.2).sub.m -- where m is an integer having a value of from 2 to 5; or Y.sub.3 and Y.sub.4 when taken together represent a methylene group; or Y.sub.7 and Y.sub.8 when taken together represent a methylene group; where Y.sub.2 and Y.sub.6, or Y.sub.2 and Y.sub.7, when taken together may represent the group --(CR.sub.1 R.sub.2).sub.n -- where n is an integer having a value of from 1 to 4 and wherein any of the groups --CR.sub.1 R.sub.2 -- may be replaced by an oxygen, sulfur or nitrogen atom; where Y.sub.5 and Y.sub.8, or Y.sub.5 and Y.sub.3, or Y.sub.3 and Y.sub.8, when taken together may represent the group --(CR.sub.1 R.sub.2).sub.r -- where r is an integer having a value of from 1 to 5 and wherein any of the groups --CR.sub.1 R.sub.2 -- may be replaced by an oxygen, sulfur or nitrogen atom; and where Y.sub.5 and Y.sub.6 when taken together represent the group .dbd.CR.sub.4 R.sub.5 where R.sub.4 and R.sub.5, which may be the same or different, are each selected from the group consisting of hydrogen and Y.sub.3, with the proviso that R.sub.4 and R.sub.5 cannot be a hydroxyl; and where R.sub.4 and Y.sub.2 when taken together may represent the group --(CR.sub.1 R.sub.2).sub.s -- where s is an integer having a value of from 1 to 3; and where the group R represents any of the typical side chains known for vitamin D type compounds.

More specifically R can represent a saturated or unsaturated hydrocarbon radical of 1-35 carbons, that may be straight-chain, branched or cyclic and that may contain one or more additional substituents, such as hydroxy- or protected-hydroxy groups, fluoro,

carbonyl, ester, epoxy, amino or other heteroatomic groups. Preferred side chains of this type are represented by the structure below ##STR7## where the stereochemical center (corresponding to C-20 in steroid numbering) may have the R or S configuration, (i.e. either the natural configuration about carbon 20 or the 20-epi configuration), and where Z is selected from Y, --OY, --CH.sub.2 OY, --C.tbd.CY and --CH.dbd.CHY, where the double bond may have the cis or trans geometry, and where Y is selected from hydrogen, methyl, --COR.sub.10 and a radical of the structure: ##STR8## where x and y, independently, represent the integers from 0 to 5, where R.sub.6 is selected from hydrogen, deuterium, hydroxy, protected hydroxy, fluoro, trifluoromethyl, and C.sub.1-5 -alkyl, which may be straight chain or branched and, optionally, bear a hydroxy or protected-hydroxy substituent, and where each of R.sub.7, R.sub.8, and R.sub.9, independently, is selected from deuterium, deuteroalkyl, hydrogen, fluoro, trifluoromethyl and C.sub.1-5 alkyl, which may be straight-chain or branched, and optionally, bear a hydroxy or protected-hydroxy substituent, and where R.sub.6 and R.sub.7, taken together, represent an oxo group, or an alkylidene group, .dbd.CR.sub.7 R.sub.8, or the group --(CH.sub.2).sub.p --, where p is an integer from 2 to 5, and where R.sub.8 and R.sub.9, taken together, represent an oxo group, or the group --(CH.sub.2).sub.q --, where q is an integer from 2 to 5, and where R.sub.10 represents hydrogen, hydroxy, protected hydroxy, or C.sub.1-5 alkyl and wherein any of the CH-groups at positions 20, 22, or 23 in the side chain may be replaced by a nitrogen atom, or where any of the groups --CH(CH.sub.3)--, --CH(R.sup.3)--, or --CH(R.sup.2)-- at positions 20, 22, and 23, respectively, may be replaced by an oxygen or sulfur atom.

The wavy line to the substituent at C-20 indicates that the carbon 20 may have either the R or S configuration."

Formula I when Y_7, Y_8, Y_4, Y_3, Y_2, Y_1 are all Hydrogen, and Y_6 and Y_5 when taken together represent the group ==CR_4R_5 where R_4 and R_5 are hydrogen, and R is the 20S vitamin D_3 alkyl group then the currently claimed compound, (20S)-1α-hydroxy-2-methylene-19-nor-vitamin D_3 is achieved. Formula I is a genus to the particular species currently claimed. In col. 12 lines 3-30, the preferred analogs section entitled 10b-Substitution exemplifies related compounds to the currently claimed compound with the difference being the presence of a 10β-substituent (U) which can be a methyl group etc...(see col. 9 lines 50-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to select the currently claimed compound as it is broadly disclosed in the genus of DeLuca et al. (as set forth above) and thus one of ordinary skill would expect it to posses increased biological activity as compared to 1α-hydroxylated vitamin D, as suggested by DeLuca et al. Further DeLuca et al. exemplify an embodiment that is closely related to the currently claimed compound (see above).

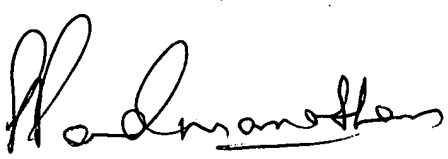
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER